proposed rule to implement section 116 of the Modernization Act by revising current regulations at 21 CFR 314.70 on supplements and other changes to an approved application. In that same issue of the **Federal Register** (64 FR 34660), FDA published a notice of availability of a draft guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' On August 19, 1999, FDA held a public meeting to discuss and receive comments on the proposed regulations and the draft guidance. (On August 5, 1999, a notice of the meeting was published in the **Federal Register** (64 FR 42625).)

The period for public comment on the proposed regulations closed on September 13, 1999, and FDA is currently reviewing the comments and preparing a final rule. The comment period for the draft guidance closed on August 27, 1999, and FDA has considered these comments when preparing the guidance that is the subject of this request for emergency processing.

FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506A of the act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. The use of normal information clearance procedures would likely result in the prevention or disruption of this collection of information because section 506A takes effect on November 21, 1999. After November 20, 1999, and until final regulations are issued revising 21 CFR 314.70, section 506A of the act will be the sole basis for FDA's regulation of postapproval manufacturing changes for products approved under NDA's or ANDA's. The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product.

Dated: October 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Programs for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is initiating of two new training programs: The Regulatory Project Manager Site Tours and the Regulatory Project Manager Shadowing Program. These programs are intended to give the Center for Drug Evaluation and Research's (CDER's) regulatory project managers an opportunity to tour pharmaceutical facilities and shadow their industry counterparts. Both the tour and shadowing programs are intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER for more information.

DATES: Pharmaceutical companies may request training program information at any time.

FOR FURTHER INFORMATION CONTACT: Deborah L. Kallgren, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5481, FAX 301–827–3132.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is initiating two new training programs to give regulatory project managers the opportunity to tour pharmaceutical facilities and shadow their industry regulatory/project management counterparts. The goals are: (1) To provide first hand exposure to industry's drug development processes, and (2) to provide a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Project Manager Site Tours and Regulatory Project Manager Shadowing Program

A. Regulatory Project Management Site Tours

In this program, over a 2-day period, small groups (six or less) of project managers accompanied by a senior level regulatory project manager may observe operations of pharmaceutical manufacturing, packaging facilities and pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

B. Regulatory Project Manager Shadowing Program

In this program, over a 2- to 3-day visit, regulatory project managers will accompany their industry counterparts in their day-to-day activities. The primary objective of the shadowing program is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management and team techniques and processes employed by the pharmaceutical industry, professional and personal growth, and enhanced job satisfaction and performance through increased understanding of the industry processes and procedures that directly relate to their jobs.

C. Site Selection

All travel expenses associated with the site tours and/or shadowing programs will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in learning more about these training opportunities, please contact Deborah L. Kallgren (address above).

Dated: October 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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